

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

**REMARKS**

**Summary of the Office Action**

The Specification is objected to because of certain informalities.

The drawings are objected to because reference character “3a” refers to both a “helical spring” and a “head portion.”

Claim 6 is objected to because of an informality.

Claim 7 stands rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention.

Claims 1, 2, 4, 7, and 8 stand rejected under 35 U.S.C § 102(b) as allegedly being anticipated by U.S. Patent No. 4,413,989 to Schjeldahl *et al.* (“Schjeldahl”).

Claims 1, 2, and 3 stand rejected under 35 U.S.C § 102(b) as allegedly being anticipated by U.S. Patent No. 4,616,653 to Samson *et al.* (“Samson”).

Claims 1, 2, 4, and 6 stand rejected under 35 U.S.C § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,409,470 to McIntyre *et al.* (“McIntyre”) in view of U.S. Patent No. 6,132,289 to Cornish *et al.* (“Cornish”) and further in view of U.S. Patent No. 5,465,733 to Hinohara *et al.* (“Hinohara”).

**Summary of the Response to the Office Action**

The non-final Office Action dated February 13, 2003, has been reviewed and the comments of the U.S. Patent Office have been considered. Applicant has amended claims 1, 3, 6, and 7, and cancelled claim 2 without prejudice or disclaimer in order to clarify the claimed invention and to expedite the prosecution of this Application. Also, Applicant has added new claims 9-12. Thus, claims 1 and 3-12 remain pending and are respectfully submitted for reconsideration by the Examiner.

**All Claims Recite Allowable Subject Matter**

*Objections to the Specification*

The disclosure is objected to for various informalities. Applicant amended the Specification to address the Examiner's objections. In particular, the "head portion" is now designated by reference numeral "4a", "mire finish" was amended to "mirror finish," and "carves" are designated by the reference numeral 12. Accordingly, Applicant respectfully requests the Examiner to withdraw the objection to the Specification.

*Objections to the Drawings*

The drawings are objected to because reference numeral "3a" refers to both a "helical spring" and a "head portion." Applicant submits herewith substitute drawings for FIGS. 1-4 and 10 that change the reference numeral designating the head portion to "4a" with a concurrently filed paper entitled "Transmittal of Substitute Drawings." Also, Applicant proposes changing the reference numeral for the diameter reduced forward helical spring in Fig. 4 from "3A" to "3c." No new matter is entered by entry of the substitute drawings. In addition, these proposed changes to the reference numerals are reflected in amendments to the Specification.

Accordingly, Applicant respectfully requests approval of the substitute drawings and the withdrawal of the objection to the drawings.

*Objection to Claim 6*

Claim 6 was objected to by the Examiner because of an informality. As a result, Claim 6 has been amended by substituting the phrase “which fit into” with “which fits into,” so that the verb now agrees with the subject, “grooves.” Accordingly, Applicant respectfully requests the Examiner to withdraw the objection to amended claim 6.

*Rejection Under 35 U. S.C. § 112*

Claim 7 stands rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Claim 7 has been amended to make it more readily apparent that the claim term “magnitude” refers to the coefficient of static friction produced between the front catheter engagement portion and the balloon catheter. As a result, Applicant respectfully requests the Examiner to withdraw the rejection of amended claim 7 under § 112, second paragraph.

*Rejection Under 35 U. S.C. § 102(b)—Schjeldahl and Samson*

Claims 1, 4, 7, and 8 stand rejected under 35 U.S.C § 102(b) as allegedly being anticipated by Schjeldahl. Claims 1 and 3 stand rejected under 35 U.S.C § 102(b) as allegedly being anticipated by Samson. Applicant traverses the rejections under § 102 because the references cited by the Office Action fail to teach or suggest features of the claimed invention as a whole.

Independent claims 1 and 9 recite an elongated and flexible medical guide wire having a combination of features including a balloon catheter that is provisionally connected to a front catheter engagement portion formed by either a mirror-shaped barrel portion or an ellipsoidal helical spring so that the balloon catheter is concurrently inserted with the medical guide wire into a blood vessel. Support for these features are provided by the Applicant's originally filed Specification at, for example, page 8, lines 2-9, and page 14, lines 8-15.

In contrast, Schjedahl states at col. 8, lines 39-51, that a guide catheter 20 is advanced to the appropriate coronary ostium, then the catheter assembly 10—surrounded by the deflated expander 30—is routed through the guide catheter 20 and positioned in the stenosed region of the coronary artery. Looking at FIG. 1, both the guide catheter 20 and catheter assembly 10 are guided over the pressure sensing tube or core wire 36. Accordingly, Applicant respectfully submits that Schjedahl does not teach or suggest at least the feature of “the provisionally connected balloon catheter is inserted into a blood vessel concurrently with the medical guide wire into said blood vessel” as recited in claims 1 and 9.

Moreover, Samson discloses a balloon catheter having a non-removable guide wire. Samson states at col. 1, lines 35-38 that “it is an object of the present invention to provide a balloon dilatation catheter with an advanceable non-removable guide wire.” Moreover, Samson also states at col. 4, lines 3-5 that “the only disadvantage being that the guide wire cannot be removed.” Further, one having ordinary skill in the art would not modify Samson with a removable guide wire because Samson states at col. 1, lines 27-34 the need for inserting and removing the guide wire limits the reduction of the diameter of collapsed balloon profiles. Thus, Samson fails to teach or suggest at least the feature of the balloon catheter provisionally connected to the front engagement portion.

Furthermore, amended claim 1 recites that the front engagement portion is “formed from a mirror-finished barrel shaped portion,” while newly added claim 9 recites that the front engagement portion is “formed by an ellipsoidal helical spring.” Applicant respectfully submits that neither Schjedahl nor Samson disclose either one of these features from claim 1 or 9. Accordingly, the references relied upon by the Office Action also fail to teach or suggest these features of claims 1 and 9 as well.

*MPEP § 2131* states that a claim is anticipated only if each and every element as set forth in the claim is found in a single reference. As noted above, the references of Schjedahl and Samson cited by the Office Action fail to teach every feature of the claimed invention as recited in claim 1 and 9 as a whole. Accordingly, Applicant respectfully requests the Examiner to withdraw the rejection of claim 1 under 35 U.S.C. § 102(b).

*Rejection Under 35 U. S.C. § 103(a)—McIntyre in view of Cornish and Hinohara*

Claims 1, 4 and 6 stand rejected under 35 U.S.C § 103(a) as allegedly being unpatentable over McIntyre in view of Cornish and further in view of Hinohara. Applicant traverses this rejection because the Office Action fails to establish a *prima facie* case of obviousness.

The Office Action states at page 10, paragraph 10 that McIntyre discloses a medical guide wire comprising an elongated and flexible core member, a front catheter engagement portion provided around the core member, the front catheter engagement portion capped with a balloon catheter to provisionally connect the balloon catheter so that the balloon catheter is inserted concurrently at the time when introducing a medical guide wire into the blood vessel. The Office Action concedes that McIntyre fails to disclose the front catheter engagement portion being formed into a bulge shape of a front engagement portion that is formed by either a mirror-

finished barrel shaped portion or an ellipsoidal helical spring. The Office Action relies upon the teachings of Cornish and Hinohara in an attempt to cure the deficiencies of McIntyre so as to reach the claimed invention as a whole. Cornish and Hinohara, however, fail to cure the deficiencies identified in McIntyre above.

The Office Action states that it would have been obvious for one having skill in the art to modify McIntyre with the helical spring 20 of Cornish in view of the teachings of Hinohara. Applicant submits that the modification proposed by the Office Action appears to render McIntyre unsatisfactory for its intended purpose. McIntyre shows in Fig. 2 that a portion of inner tube 36, which has to maintain a substantially uniform diameter in order to permit the wire guide 12 to both extend through spacer element 44 within the distal neck 42 of balloon 38 and have the proximal end 24 engage the threads 54. Consequently, if the proximal segment 24 of helical coil 20 of McIntyre were modified with the tapered section 25 of Cornish, then it appears that helical coil 20 would not engage the threads 54 to detachably connect the core wire 12 to the balloon 38. *MPEP* § 2143.01 states that if a proposed modification renders the invention disclosed in the reference unsatisfactory for its intended purpose, then there is no suggestion or motivation to combine references. Accordingly, Applicant submits that the Office Action does not establish a *prima facie* case of obviousness.

Furthermore, assuming *arguendo*, even if McIntyre could be modified as proposed by the Office Action, the Applicant respectfully submits that modifying McIntyre with the helical spring 20 of Cornish would still not teach or suggest all the features of the claimed invention as a whole. As noted above, claim 1 and 9 recite respectively a front engagement portion either “formed from a mirror-finished barrel shaped portion,” or “formed by an ellipsoidal helical spring.” Applicant submits that neither the helical spring 20 of Cornish nor the coil spring 24 of

Hinohara is either barrel-shaped or ellipsoidal. In addition, neither Cornish nor Hinohara appear to show a “mirror-finished” front engagement portion. Accordingly, the combination proposed by the Office Action fails to teach or suggest features of the claimed invention as a whole as recited in claims 1 and 9. Therefore, claims 1 and 9 are allowable over the combination of relied-upon references to McIntyre, Cornish, and Hinohara, either singularly or in combination thereof.

Claims 3-8 and 10-12, which ultimately depend from one of allowable independent claims 1 or 9, are allowable for at least the same reasons as claims 1 and 9, as well as for reciting additional features. Thus, Applicant respectfully submits that claims 1 and 3-12 are in condition for allowance.



**CONCLUSION**

In view of the foregoing amendments and remarks, Applicant respectfully requests the reconsideration and reexamination of this Application and the prompt allowance of pending claims 1 and 3-12. Applicant invites the Examiner to contact Applicant's undersigned representative if there are any issues that can be resolved via telephone conference.

Attached hereto is the paper "Transmittal of Substitute Drawings" and substitute drawings for FIGs. 1-4 and 10.

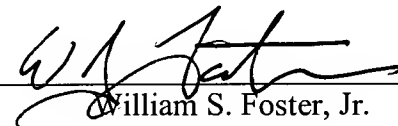
**EXCEPT** for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-0310.

Respectfully submitted,

**MORGAN, LEWIS & BOCKIUS LLP**

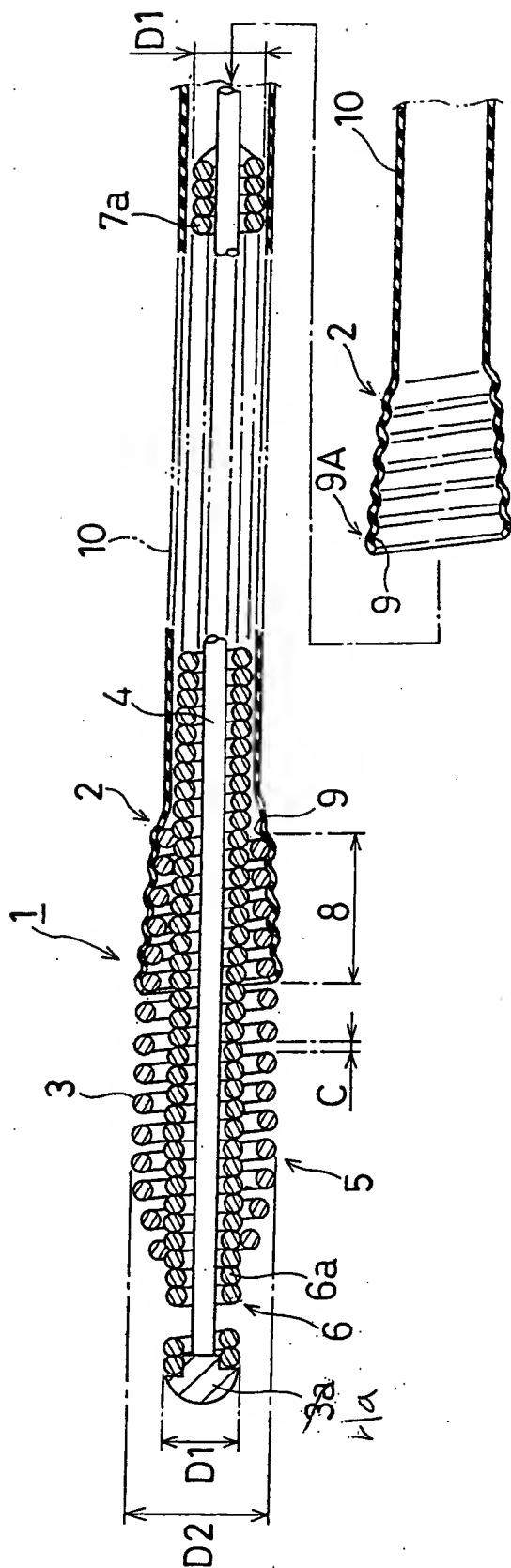
Date: July 10, 2003

By:

  
William S. Foster, Jr.  
Reg. No. 51,695

**Customer No. 009629**  
**MORGAN, LEWIS & BOCKIUS LLP**  
1111 Pennsylvania Avenue, NW  
Washington, DC 20004  
Tel.: 202.739.3000  
Fax: 202.739.3001

Fig.1



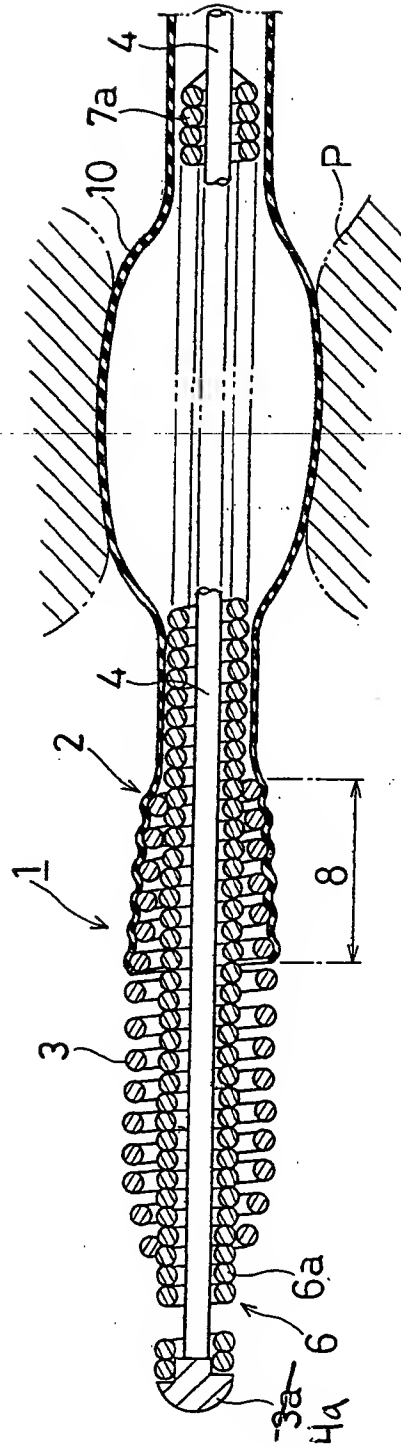


Fig. 3

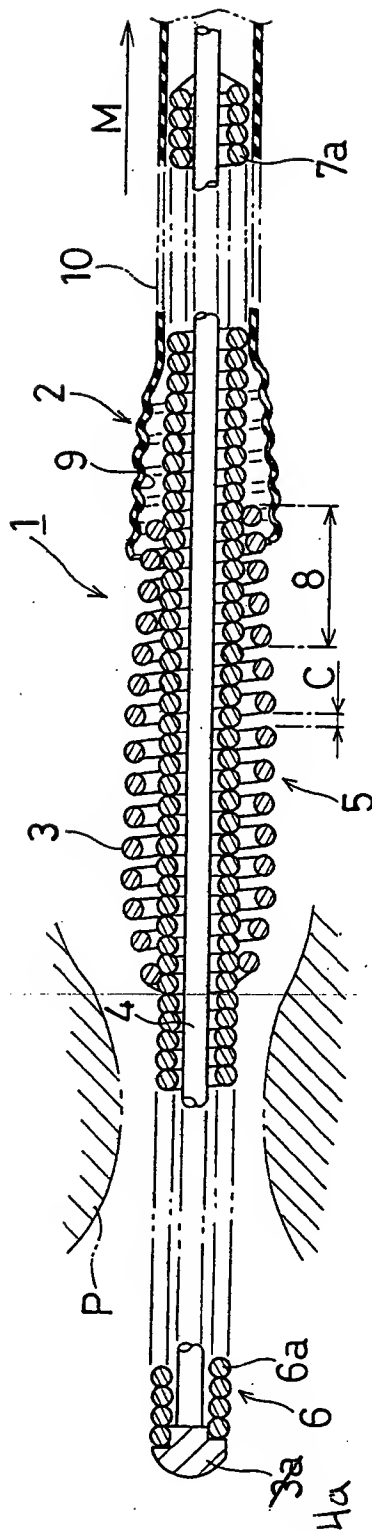


Fig. 4

